

fact, the existence of any such privilege does not affect BAYER'S obligation to comply with this Agreement.

- 11) This Agreement is intended to be for the benefit of the Parties only and, except as stated herein, the Parties do not by this instrument release any claims against any other person or entity, including any individual or entity that purchased drugs or biological products from BAYER.
- 12) The STATE acknowledges BAYER's cooperation in the STATE's investigation of drug pricing practices and agrees to communicate the nature and extent of this cooperation to other parties upon the request of BAYER. The making of this Agreement, and BAYER's provision of information pursuant to it, shall not be construed by the STATE as a basis for the exclusion of any of BAYER's products from the STATE's formulary.
- 13) Concurrent with the execution of this Agreement and payment of the Settlement Amount, the STATE agrees to dismiss with prejudice any lawsuit against BAYER, including any STATE qui tam "whistleblower" lawsuit currently pending against BAYER in the courts of the STATE, relating to the Covered Conduct.
- 14) Nothing in this Agreement shall be construed to abrogate or alter any existing obligation of BAYER pursuant to State law.
- 15) This Agreement, including all exhibits, constitutes the complete agreement between the Parties and may not be amended except by written consent of the Parties.
- 16) Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

17) This agreement is governed by the laws of the State of New York.

18) Unless otherwise stated in writing subsequent to the Effective Date of this Agreement, all notifications and communications made pursuant to this Agreement shall be submitted to the entities listed below:

**STATE :**

[For the submission of average sale price data]

Pharmacy Director  
Pharmacy Policy & Operations  
40 Marlboro Road  
Delmar, New York 12054

[For legal notices and all other purposes]

State of New York  
Office of the Attorney General  
Medicaid Fraud Control Unit  
120 Broadway  
13th Floor  
New York, New York 10271

**BAYER:**

Assistant General Counsel  
Bayer Corporation Pharmaceutical Division  
400 Morgan Lane  
West Haven, CT 06516

19) BAYER represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

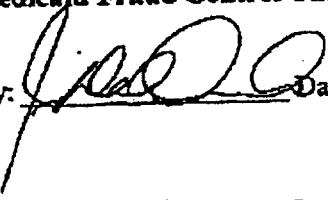
20) The undersigned individuals signing this Agreement on behalf of BAYER represent and warrant that they are authorized by BAYER to execute this Agreement. The undersigned STATE signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

21) Each party agrees to perform any further acts and to execute and deliver any further documents reasonably necessary to carry out this Agreement. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

22) The parties have read the foregoing Agreement and accept and agree to the provisions contained therein and hereby have caused this Agreement to be signed as of the day and date adjacent to their signature.

23) The Effective Date of this Agreement shall be the date upon which all the parties below have executed this Agreement.

State of New York  
Office of Attorney General  
Medicaid Fraud Control Unit

By:  Date: 3/7/01

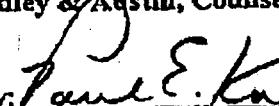
Title: Deputy Attorney General

Bayer Corporation

By:  Date: 8/6/01

Title: Vice President, Assistant General Counsel

Sidley & Austin, Counsel for BAYER

By:  Date: 8/11/01

Paul E. Kalb, Esq.  
L Scott Bass, Esq.  
Robert Fabrikant, Esq.

**Exhibit "A"**  
**Participating States**

ALABAMA  
ALASKA  
ARKANSAS  
CALIFORNIA  
COLORADO  
CONNECTICUT  
DELAWARE  
FLORIDA  
GEORGIA  
HAWAII  
IOWA  
ILLINOIS  
INDIANA  
KANSAS  
KENTUCKY  
LOUISIANA  
MASSACHUSETTS  
MARYLAND  
MAINE  
MICHIGAN  
MINNESOTA  
MISSOURI  
MISSISSIPPI  
MONTANA  
NORTH CAROLINA  
NEW HAMPSHIRE  
NEW JERSEY  
NEW MEXICO  
NEVADA  
NEW YORK  
OHIO  
OKLAHOMA  
OREGON  
PENNSYLVANIA  
RHODE ISLAND  
SOUTH CAROLINA  
SOUTH DAKOTA  
TEXAS  
UTAH  
VIRGINIA  
VERMONT  
WASHINGTON  
WISCONSIN  
WEST VIRGINIA.  
WYOMING

**Exhibit "B"**  
**Threshold States**

ALABAMA  
ARKANSAS  
CALIFORNIA  
CONNECTICUT  
FLORIDA  
ILLINOIS  
LOUISIANA  
MASSACHUSETTS  
MARYLAND  
MICHIGAN  
MINNESOTA  
MISSOURI  
NORTH CAROLINA  
NEW JERSEY  
NEW YORK  
OHIO  
PENNSYLVANIA  
SOUTH CAROLINA  
TEXAS  
VIRGINIA  
WASHINGTON  
WISCONSIN

**Exhibit "C"**  
**Certification Form**

**CERTIFICATION**

The undersigned, a high managerial agent of Bayer Corporation, hereby certifies that the attached average sale price information has been communicated to First DataBank and that it has been calculated in accordance with the methodology described herein. I further acknowledge that the average sale prices so reported will be filed with and used in the administration of the State of New York Medicaid program.

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Signature

---

Title

---

Date

## **Exhibit 2**

**STATE SETTLEMENT AGREEMENT AND RELEASE**

**I. PARTIES**

This Settlement Agreement ("Agreement") is entered into by the State of New York and Bayer Corporation ("Bayer"), an Indiana corporation with a principal place of business in Pittsburgh, Pennsylvania, hereinafter referred to as "the Parties."

**II. PREAMBLE**

As a preamble to this State Agreement, the Parties agree as follows:

A. This Agreement addresses the claims against Bayer for the conduct described in filings in United States v. Bayer Corporation, Criminal Action No. [to be assigned] (District of Massachusetts) (the "Criminal Action"), and in filings in United States ex rel. Couto v. Bayer Corporation, Civil Action No. 00-CV-10339 (District of Massachusetts) (the "Civil Action") for the conduct alleged in Preamble Paragraph F below.

B. On or before April 16, 2003, or some other date as may be determined by the Court, Bayer has agreed to or has entered a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to a one-count Information alleging a violation of Title 21, United States Code, Sections 331(p), 333(a)(2) and 360(j) by failing to list a drug product with the FDA between August and December 1995, namely, Cipro, that was private labeled by Bayer for Kaiser Permanente Medical Care Program ("Kaiser").

C. At all relevant times, Bayer marketed and sold pharmaceutical products nationwide, including among other drugs, two prescription drug products: (1) ciprofloxacin hydrochloride tablets, an antibiotic, marketed under the brand name Cipro®; and (2) nifedipine extended release tablets, an anti-hypertensive, marketed under the brand name Adalat CC® (collectively, "the drugs"). Bayer sold the drugs to various customers including, among others, health maintenance organizations ("HMOs"), hospitals, long term care providers, and chain pharmacies. Two HMOs that purchased the drugs from Bayer were Kaiser and PacifiCare

Health Systems ("Pacificare"). Pacificare purchased the drugs from Bayer through Prescription Solutions, a pharmacy benefit manager and wholly owned subsidiary of Pacificare.

D. Effective August 1995, Bayer agreed to private label Cipro for Kaiser and to sell the private labeled Cipro to Kaiser at a discounted price. The term "private labeled" as used herein, means drug product that Bayer sold to a purchaser to which Bayer affixed a label that substituted the purchaser's national drug code ("NDC") for Bayer's NDC number. Effective April 1997, Bayer agreed to private label Adalat CC for Kaiser and to sell the private labeled Adalat CC to Kaiser at a discounted price. Effective October 1998, Bayer agreed to private label Adalat CC for Pacificare and to sell the private labeled Adalat CC to Pacificare at a discounted price.

E. At all material times, Bayer participated in the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. As a participant in the Medicaid Rebate Program, Bayer entered into a rebate agreement with the Secretary of the Department of Health and Human Services, which agreement is administered by the Health Care Financing Administration ("HCFA"), currently known as the Center for Medicare and Medicaid Services ("CMS"), and Bayer's drug products were covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A); 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Rebate Program and rebate agreement with HCFA, Bayer generally agreed: (i) to report quarterly to HCFA its average manufacturer price and Best Price for its drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the average manufacturer price and Best Price, or a minimum rebate percentage of the average manufacturer price, as further defined in 42 U.S.C. § 1396r-8(c)(1).

F. The State of New York contends that it has certain civil claims against Bayer Corporation under the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, the Drug Pricing Program, 42 U.S.C. § 256b, other federal and state statutes, and/or common law doctrines for engaging in the following conduct:

- (i) The State of New York contends that, from Third Quarter 1995 through Third Quarter 2000, Bayer knowingly misreported its Best Price to HCFA and underpaid its Medicaid rebates for Cipro tablets by omitting the price of Cipro that was private labeled for Kaiser from its determination of Best Price;
- (ii) The State of New York contends that, from Second Quarter 1997 through Third Quarter 2000, Bayer knowingly misreported its Best Price to HCFA and underpaid its Medicaid rebates for Adalat CC by omitting the price of Adalat CC that was private labeled for Kaiser and PacifiCare from its determination of Best Price;
- (iii) The State of New York contends that, in May and June 1999, Bayer knowingly submitted false statements or records to the Office of Inspector General, Office of Audit Services, Department of Health and Human Services ("OIG-OAS") by (a) omitting material information about the price of Cipro tablets that was private labeled for Kaiser; (b) falsely stating that a higher priced package of Cipro was private labeled for Kaiser when it was not; and (c) falsely stating that the actual price at which Bayer sold Cipro to Kaiser was higher than Bayer's reported Best Price;
- (iv) The State of New York contends that, in First Quarter 1998, Bayer knowingly misreported its Best Price to HCFA and underpaid its Medicaid rebates for Adalat CC by omitting a \$100,000 payment made by Bayer to Prescription Solutions in connection with Adalat CC;
- (v) The State of New York contends that Bayer knowingly failed to list the Cipro that Bayer private labeled for Kaiser with the FDA to conceal the private labeling arrangement from the FDA and customers of Bayer's Cipro.

Bayer's conduct as described in the Criminal Action, the currently pending claims in the Civil Action, and this Preamble Paragraph are hereafter referred to as the "Covered Conduct."

G. The State of New York represents that it does not have an administrative claim for exclusion against Bayer under the provisions for mandatory exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(a) or corresponding state statutes, for Bayer's conviction in the Criminal Action or for the Covered Conduct, but alleges that it does have certain administrative claims for exclusion against Bayer under the provisions for permissive exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(b) and corresponding state statutes, for the Covered Conduct.

H. Other than such admissions as Bayer makes in connection with its plea to the information to which Bayer has agreed to enter a plea of guilty, which Bayer admits, Bayer denies the remaining allegations of the United States, relator(s) and the State of New York as set forth herein. This Agreement does not constitute an admission by Bayer or evidence of any liability or wrongful conduct.

I. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Bayer agrees to pay to the United States and to the Escrow Agent described below for distribution to the states and the District of Columbia that execute a state settlement agreement that has also been executed by Bayer ("Participating States") the sum of two-hundred, forty-two million, one-hundred twenty-six thousand, five-hundred eighty dollars (\$242,126,580)

(the "Medicaid Settlement Amount") and any pre-transfer interest as set forth in Section III.1.A and III.1.B herein. Payments to the United States and to the Participating States shall be made pursuant to the following terms and conditions:

A. Bayer has agreed to pay to the United States the sum of one-hundred, thirty-three million, one-hundred and sixty-nine thousand, six-hundred and nineteen dollars (\$133,169,619) (the "Federal Medicaid Settlement Amount"), which represents the federal share of the Medicaid Settlement Amount and the share of the Medicaid Settlement Amount payable to the relator(s) in certain federal False Claims Act lawsuit(s). The Federal Medicaid Settlement Amount, plus any pre-transfer interest pursuant to Section III.1.A of the Federal Agreement, shall be paid pursuant to a civil settlement agreement entered between Bayer and the United States (the "Federal Agreement").

B. Bayer agrees to deposit into an escrow account the sum of one-hundred and eight million, nine-hundred, fifty-six thousand, nine-hundred and sixty-one dollars (\$108,956,961) (the "State Medicaid Settlement Amount"), which represents the state-funded portions of the claims settled for the Medicaid programs of all states (except Arizona) and the District of Columbia. Bayer shall pay the State Medicaid Settlement Amount, plus any pre-transfer interest pursuant to Section III.1.B of the Federal Agreement, into the escrow account no later than seven business days after Bayer receives written transfer instructions from the negotiating team for the National Association of Medicaid Fraud Control Units ("NAMFCU Negotiating Team") and following the latest of the dates on which the following occurs: (1) the Federal Agreement is fully executed by the Parties and delivered to Bayer's attorneys, (2) the Escrow Agreement is executed by or on behalf of the Participating States and Bayer, and (3) the Court accepts the Fed. R. Crim. P. 11(e)(1)(C) guilty plea in connection with the Criminal Action as described in Preamble Paragraph II.B, and imposes the agreed upon sentence. The escrow account into which Bayer shall deposit the State Medicaid Settlement Amount shall be an account under the custody and control of the Medicaid Fraud Control Unit of the State of New

York, which shall be designated by the NAMFCU Negotiating Team and which shall act as Escrow Agent and shall retain such funds until their release in accordance with the Escrow Agreement entered into between Bayer and the Medicaid Fraud Control Unit of the State of New York.

C. The total portion of the Medicaid Settlement Amount paid by Bayer in settlement for alleged injury to the Medicaid Program for the State of New York is \$17,256,166.63, consisting of a portion paid to the State of New York under this Agreement and another portion paid to the federal government as part of the Federal Settlement. The individual portion of the State Medicaid Settlement Amount allocable to the State of New York is the sum of \$9,133,252.63 ("Individual State Medicaid Settlement Amount").

D. The State of New York shall be entitled to disbursement of its Individual State Medicaid Settlement Amount from the escrow account pursuant to the terms of the Escrow Agreement, which is attached hereto as Exhibit A and is incorporated by reference herein.

2. In consideration of this Agreement and payment set forth herein and subject to the exceptions from release set forth in Paragraph 3 below, the State of New York on behalf of itself, its officers, agents, agencies and departments shall release and forever discharge Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, from any civil or administrative claims for damages or penalties that the State of New York has or may have relating to the Covered Conduct. The payment of the Medicaid Settlement Amount fully discharges Bayer from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the State of New York specifically does not herein release Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, and its current and former directors, officers, agents and employees from any and all of the following: (a) any potential criminal, civil or administrative claims arising under State of New York revenue codes; (b) any criminal

liability not specifically released by this Agreement; (c) any civil or administrative liability that Bayer has or may have under any state statute, regulation, or rule not covered by the release; (d) any liability to the State of New York (or its agencies) for any conduct other than the Covered Conduct; (e) any claims based upon such obligations as are created by this State Settlement Agreement.

4. In consideration of the obligations of Bayer set forth in this Agreement and payment set forth herein and except as reserved in Paragraph 3 above, the State of New York agrees to release and refrain from instituting, directing, recommending or maintaining (a) any administrative claim; or (b) any action seeking exclusion from the State of New York's Medicaid program; against Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, for the Covered Conduct or for Bayer's conviction in the Criminal Action. Nothing in this Agreement precludes the State of New York from taking action against Bayer in the event that Bayer is excluded by the federal government, or for conduct and practices other than the Covered Conduct or the conviction in the Criminal Action. The Medicaid Fraud Control Unit for the State of New York further agrees to refrain from recommending, causing or attempting to cause any administrative action or sanction, including debarment, by any other government agency of the State of New York for the Covered Conduct or for the conviction in the Criminal Action. The State of New York does not have the authority to release Bayer from any claims or actions which may be asserted by private payors or insurers, including those that are paid by a State's Medicaid program on a capitated basis, which are not a party to the Medicaid Rebate Program.

5. The making of this Agreement shall not be construed by the State of New York as a basis for the exclusion of any of Bayer's products from the State of New York's formulary or as a basis for a change in status regarding prior authorization.

6. The State of New York agrees to dismiss with prejudice any lawsuit specifically as to Bayer, including any state qui tam "whistleblower" lawsuit, in which the state has

intervened and/or has the authority to dismiss, currently pending against Bayer in the courts of the State of New York, relating to the Covered Conduct.

7. This Agreement is expressly conditioned upon acceptance of Bayer's plea of guilty in the Criminal Action. In consideration of the acceptance of Bayer's plea of guilty in the Criminal Action, the State of New York agrees that it shall not investigate, prosecute, or refer for prosecution or investigation to any agency, Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, for the Covered Conduct.

8. Bayer fully and finally releases the State of New York, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which Bayer has asserted, could have asserted, or may assert in the future against the State of New York, its agencies, employees, servants, and agents, related to or arising from the investigation and prosecution of the Covered Conduct up to the effective date of this Settlement Agreement.

9. Nothing in this agreement shall preclude either Bayer or the State of New York from pursuing any rights they have pursuant to the Medicaid Rebate Program as to adjustments to Rebate Payments, except to the extent that no adjustment shall be made to Best Price based upon Covered Conduct, which this agreement settles.

10. Bayer waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Settlement Agreement bars a remedy sought in such criminal prosecution or administrative action. Provided, however, that nothing in this paragraph is intended to, or will operate to, limit the scope of Paragraph 7, in which the State of New York agrees not to prosecute or investigate Bayer for certain conduct.

11. Except as otherwise specified herein, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity, including but not limited to any individual or entity that purchased Cipro and Adalat from Bayer.

12. Nothing in any provision of this Agreement constitutes an agreement by the State of New York concerning the characterization of the Medicaid Settlement Amount for purposes of the state internal revenue laws.

13. In addition to all other payment and responsibilities under this Agreement, Bayer agrees to pay all reasonable travel costs and expenses of the NAMFCU Negotiating Team. Bayer will pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units after the Participating States execute this Agreement.

14. Bayer covenants to cooperate fully and truthfully with the State of New York in any ongoing investigation or investigation commenced within five years of the effective date of this Agreement of individuals and entities not specifically released by this Agreement (including any parties with whom Bayer has or has had a business or professional relationship, including but not limited to vendors, contractors, partners, joint venturers, physicians, and referral sources) relating to the Covered Conduct.

15. Notwithstanding any provision of this Agreement, Bayer is not required to (1) request of its present or former officers, directors, employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) take any action against its directors, employees or agents for following their attorney's advice or for failing to submit to an interview or otherwise cooperate with the State of New York; or (3) waive any privilege or claim of work product. The failure of any individual to submit to an interview or otherwise to refuse to cooperate with the State of New York shall not constitute a breach of this Agreement by Bayer.

16. Bayer shall enter into an Addendum to its existing Corporate Integrity Agreement with HHS-OIG in connection with this matter.

17. Bayer represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

18. The undersigned Bayer signatory represents and warrants authorization by the Board of Directors to execute this Agreement. The undersigned State of New York signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the State of New York through their respective agencies and departments.

19. This Agreement is governed by the laws of the State of New York.

20. This Agreement is effective on the date of signature of the last signatory to the Agreement.

21. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties; provided, however, this Agreement shall not apply to the products of an acquiring company or a company merging with Bayer except to the extent such company, as a result of the acquisition of or merger with Bayer, becomes involved in the sales, marketing or pricing of, or Medicaid Drug Rebate program obligations associated with, drug and biologic products for which the Federal health care programs provide reimbursement ("Government Reimbursed Products") originally manufactured by Bayer prior to the merger or acquisition, in which case the obligations of this agreement shall apply only to those products which had been Government Reimbursed Products when they were manufactured by Bayer.

22. This Agreement constitutes the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of the Parties.

23. Each party agrees to perform any further acts and to execute and deliver any further documents reasonably necessary to carry out this Agreement. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

For the State of New York:

By: William J. Conacher Dated: 8-14-03

Title: Director  
Medicaid Fraud Control Unit

BAYER CORPORATION

By: \_\_\_\_\_ Dated: \_\_\_\_\_  
JON R. WYNE  
Senior Vice President and Treasurer  
Bayer Corporation

By: \_\_\_\_\_ Dated: \_\_\_\_\_  
PAUL E. KALB  
JAMES C. STANSEL  
Sidley Austin Brown & Wood, LLP  
1501 K Street, NW  
Washington, DC 20005  
Counsel to Bayer Corporation



**U.S. Department of Justice**

*United States Attorney  
District of Massachusetts*

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Main Reception: (617) 748-3100

United States Courthouse, Suite 9200  
1 Courthouse Way  
Boston, Massachusetts 02210

April 7, 2003

I. Scott Bass, Esq.  
Paul E. Kalb, Esq.  
Nathan C. Sheers, Esq.  
Sidley Austin Brown & Wood LLP  
1501 K Street NW  
Washington, DC 20005

**Re:** Bayer Corporation

Dear Messrs. Bass, Kalb and Sheers:

This letter sets forth the Agreement between the United States Department of Justice and the United States Attorney for the District of Massachusetts (the "U.S. Attorney") (collectively, the United States Department of Justice and the U.S. Attorney shall be referred to as the "United States") and your client, Bayer Corporation ("Bayer"), an Indiana Corporation, (collectively referred to as "the Parties") as follows:

1. Guilty Plea

On or before April 16, 2003, or such other date as the Court may set, Bayer shall waive indictment and plead guilty to the Information attached hereto as Exhibit A, charging a felony violation of Title 21, United States Code, Sections 331(p), 333(a)(2) and 360(j), by failing to provide notice to the FDA of the introduction of private label Cipro for commercial distribution to Kaiser Permanente, which drug had not been included in any list previously filed by Bayer with the FDA. Bayer expressly waives any statute of limitations defense that it may have in connection with this crime. Bayer expressly and unequivocally admits that it committed the crime charged in the attached Information with the intent to defraud or mislead.

2. Sentencing Guidelines

The United States and Bayer agree that the following provisions of the United States Sentencing Guidelines ("U.S.S.G.") apply to sentencing of Bayer with respect to the Information:

- (a) pursuant to U.S.S.G. § 8C2.4(a) and 18 U.S.C. § 3571(d), the pecuniary loss intended by Bayer from the offense for criminal sentencing purposes is \$4,659,000;
- (b) pursuant to U.S.S.G. § 8C2.5, the culpability score is 6 as follows:
  - (i) base score of 5 pursuant to § 8C2.5(a);
  - (ii) add three points pursuant to § 8C2.5(b)(3)(B)(i) and/or (ii);
  - (iii) deduct 2 points pursuant to § 8C2.5(g)(2).
- (c) pursuant to § 8C2.6, the appropriate range for a multiplier is 1.2 to 2.4, and the appropriate multiplier to be applied to Bayer is 1.2.
- (d) the parties agree that there is no basis for a departure under the U.S.S.G., either upwards or downwards.

3. Agreed Disposition

The United States and Bayer agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the following sentence is the appropriate disposition of the Information:

- (a) a criminal fine in the amount of five million five hundred ninety thousand eight hundred dollars (\$5,590,800) to be paid within one week of the date of sentencing;
- (b) a mandatory special assessment of \$400 pursuant to 18 U.S.C. § 3013, which shall be paid to the Clerk of Court on or before the date of sentencing;

In light of the pending civil action, United States ex rel. George Conio v. Bayer Corporation, Civil Action 00-10339-PBS (D. Mass.) and the Civil Settlement Agreement between Bayer and others and the United States relating to the civil action which is being signed contemporaneously with this plea agreement, and attached hereto as Exhibit B, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to the victims in this case, where, as here, the loss suffered by the victims of this crime will be

recompensed fully from amounts paid as part of the Civil Settlement Agreement. See, 18 U.S.C. § 3663(a)(1)(B)(ii). Therefore, the United States agrees that it will not seek a separate restitution order as to Bayer as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

The United States may, at its sole option, be released from its commitments under this Agreement, including, but not limited to, its agreement in this paragraph regarding the appropriate disposition of this case, if at any time between its execution of this Agreement and sentencing, Bayer:

- (a) Fails to admit a complete factual basis for the plea;
- (b) Fails to truthfully admit its conduct in the offense of conviction;
- (c) Falsely denies, or frivolously contests, relevant conduct for which Bayer is accountable under U.S.S.G. § 1B1.3;
- (d) Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which Bayer is accountable under U.S.S.G. § 1B1.3;
- (e) Engages in acts which form a basis for finding that Bayer has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1; and/or
- (f) Attempts to withdraw its plea.

Bayer expressly understands that it may not withdraw its plea of guilty, unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5).

4. No Further Prosecution of Bayer

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), the United States agrees that, other than the charge in the attached Information, it shall not further prosecute Bayer for conduct which (a) falls within the scope of the Information; (b) was the subject of the investigation by the grand jury; or (c) was known to the U.S. Attorney prior to the date of execution of this letter.

The U.S. Attorney expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of Bayer, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the U.S. Attorney.

This declination is contingent on (1) the guilty plea of Bayer being accepted by the Court and not withdrawn, and (2) Bayer's performance of all of its obligations as set forth in this Agreement and the attached Civil Settlement Agreement. A breach of the Corporate Integrity Agreement and Addendum thereto (collectively "CIA"), incorporated by reference in the Civil Settlement Agreement, does not constitute a breach of this Plea Agreement, and any disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions of the CIA. If Bayer's guilty plea is not accepted by the court or is withdrawn for any reason, or if Bayer should fail to perform an obligation under this Agreement or the Civil Settlement Agreement, this declination of prosecution shall be null and void.

5. Payment of Mandatory Special Assessment

Bayer agrees to pay the mandatory special assessment to the Clerk of Court on or before the date of sentencing.

6. Cooperation

Bayer agrees to cooperate completely and truthfully with the U.S. Attorney in connection with his on-going investigation and prosecution of others for alleged violations of federal criminal law arising out of his investigation. Bayer understands and agrees that such cooperation shall include the following, if requested by the U.S. Attorney:

- (a) prompt production to the U.S. Attorney of any document or record in the possession, custody or control of Bayer relating to the subject matters of the investigation;
- (b) taking all reasonable measures available to Bayer to ensure that present and former officers, directors, agents and employees of Bayer cooperate truthfully and completely with the U.S. Attorney in connection with his on-going investigations and prosecutions
- (c) taking all reasonable measures available to Bayer to make all present and former officers and employees of Bayer available for interviews by law enforcement personnel, on reasonable notice.

Provided, however, that notwithstanding any provision of this Agreement, (1) Bayer is not required to request of its present or former officers, directors, employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) Bayer is not required to take any action against its officers, directors, employees or agents for following their attorney's advice; and (3) Bayer is not required to waive any privilege or claim of work product, except to the extent previously agreed by letters dated August 4, 2000 between AUSA Susan Winkler and Paul Kalb, Esq.; and dated June 11, 2002 between AUSA Susan Winkler and Paul Kalb, Esq. and Scott Bass, Esq.

7. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

8. Fed. R. Crim. P. 11(c)(1)(C) Agreement

Bayer's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). Bayer cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith. If the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith, this Agreement shall be null and void at the option of either the United States or Bayer.

Bayer may seek sentencing by the District Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence Bayer immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. Bayer understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

9. Civil and Administrative Liability

By entering into this Agreement, the United States does not compromise any civil or administrative liability, including but not limited to any False Claims Act or tax liability which Bayer may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

Bayer's civil liability to the United States in connection with certain of the matters under investigation by the United States is resolved in the Civil Settlement Agreement, attached as Exhibit B, according to the terms set forth in that Agreement.

Contemporaneously with the execution of this Agreement, Bayer shall enter into the CIA with the Office of Inspector General for the United States Department of Health and Human Services, attached as Exhibit C.

10. Waiver of Defenses

If Bayer's guilty plea is not accepted by the Court for whatever reason, or is later withdrawn for whatever reason, Bayer hereby waives, and agrees it will not interpose, if charges are filed within 30 days of the date on which such guilty plea is rejected or withdrawn, any defense to any charges brought against it which it might otherwise have under any statute of limitations or the Speedy Trial Act, except any such defense that Bayer may already have for conduct occurring before May 8, 1997.

**11. Breach of Agreement**

If the U.S. Attorney determines that Bayer has failed to comply with any material provision of this Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in its entirety by notifying Bayer, through counsel or otherwise, in writing. The United States may also pursue all remedies available under the law, even if it elects not to be released from its commitments under this Agreement. Bayer recognizes that no such breach by Bayer of an obligation under this Agreement shall be grounds for withdrawal of its guilty plea. Bayer understands that should it breach any material provision of this Agreement, the U.S. Attorney will have the right to use against Bayer before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by Bayer, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

Bayer understands and agrees that this 11(c)(1)(C) plea agreement and its agreed upon criminal disposition:

- (1) are wholly dependent upon Bayer's timely compliance with the provisions of the attached Civil Settlement Agreement, including the requirement in the agreement that Bayer pay to the United States and to the various state Medicaid Programs the amount of two hundred forty two million one hundred twenty six thousand five hundred eighty dollars (\$242,126,580), and that Bayer pay to the PHS entities the amount of no less than nine million four hundred eighty two thousand six hundred twenty dollars (\$9,482,620) in accord with the terms of the Civil Settlement Agreement; and that
- (2) failure by Bayer to comply fully with the terms of this Agreement or the attached Civil Settlement Agreement will constitute a breach of this Agreement.

In the event Bayer at any time hereafter breaches any material provision of this Agreement, Bayer understands that (1) the United States will as of the date of that breach be relieved of any obligations it may have in this Agreement and the attached Civil Settlement Agreement, including but not limited to the promise not to further prosecute Bayer as set forth in paragraph 4 of this Agreement; and (2) Bayer will not be relieved of its obligation to make the payments set forth in this Agreement and the attached Civil Settlement Agreement, nor will it be entitled to return of any monies already paid.

**12. Corporate Authorization**

Bayer's acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached as Exhibit D. Bayer shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the Board of Directors of Bayer Corporation, affirming that the Board of Directors has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in

connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize Bayer to plead guilty to the charge specified in the Information; and (5) voted to authorize the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. A copy of the resolution is attached as Exhibit E. Bayer agrees that either a duly authorized corporate officer or a duly authorized attorney for Bayer, at the discretion of the Court, shall appear on behalf of Bayer and enter the guilty plea and will also appear for the imposition of sentence.

**13. Who Is Bound By Agreement**

This Agreement is binding upon Bayer and the Attorney General of the United States, the United States Department of Justice, and all United States Attorneys on the matters set forth above in Paragraph 4, but does not bind the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury. A copy of the letter to United States Attorney Michael Sullivan from Michael Chertoff, Assistant Attorney General, Criminal Division, Department of Justice, authorizing this Agreement is attached as Exhibit F. Bayer understands that this Agreement does not bind any state or local prosecutive authorities.

**14. Complete Agreement**

This Agreement, together with the Civil Settlement Agreement, set forth the complete and only agreement between the Parties relating to the disposition of this matter. No promises, representations, agreements or conditions have been entered into other than those set forth in this letter and its attachments A through F. This agreement supersedes prior understandings, if any, of the parties, whether written or oral. This agreement can be modified or supplemented only in a written memorandum signed by the Parties or as agreed by the Parties on the record in court.

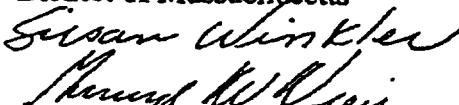
If this letter accurately reflects the Agreement entered into between the United States and your client Bayer Corporation, please have Bayer sign the Acknowledgment of Agreement below. Please also sign as Witness. Return the original of this letter to Assistant U.S. Attorney Susan G. Winkler of the United States Attorney's Office of the District of Massachusetts.

Very truly yours,

By:

  
MICHAEL J. SULLIVAN  
United States Attorney  
District of Massachusetts

By:

  
SUSAN G. WINKLER  
Deputy Chief, Health Care Fraud  
GEORGE W. VIEN  
Assistant U.S. Attorney

**#6**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	C.A. No. 01-CV-12257 (PBS)
<i>THIS DOCUMENT RELATES TO:</i>	)	HON. PATTI B. SARIS
<hr/>		
COUNTY OF SUFFOLK,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
ABBOTT LABORATORIES, INC., <i>et al.</i>	)	
	)	
Defendants.	)	
<hr/>		

**MEMORANDUM OF LAW OF CERTAIN "SUFFOLK-ONLY DEFENDANTS" IN  
SUPPORT OF MOTION TO DISMISS AMENDED COMPLAINT**

## PRELIMINARY STATEMENT

Defendants Berlex Laboratories, Inc., Forest Pharmaceuticals, Inc., Purdue Pharma L.P. and Reliant Pharmaceuticals, LLC (hereinafter "Suffolk-Only Defendants") jointly submit this Memorandum of Law in support of the Motion to Dismiss Plaintiff County of Suffolk's ("Suffolk") Amended Complaint.<sup>1</sup>

The Suffolk-Only Defendants referenced herein are not named as Defendants in the Amended Master Consolidated Complaint or in the myriad other proceedings which have been filed, most of which focus heavily on alleged abuses regarding Medicare Part B drugs.<sup>2</sup> But for each of the Suffolk-Only Defendants, Suffolk identifies only one drug at issue in the Amended Complaint, and none of these is a Medicare Part B drug.

Largely employing rhetoric only applicable to Medicare Part B situations and trumpeting governmental investigations of *other* pharmaceutical companies, Suffolk seeks to ensnare the Suffolk-Only Defendants in the expansive *In re Pharmaceutical Industry Average Wholesale Price Litigation* by making allegations which are: (1) conclusory and devoid of the factual support required by Rule 9(b), and (2) demonstrably lacking in merit and logic. Indeed, Suffolk's effort to confuse Medicare issues with Medicaid issues and to plead in generalities is a perfect illustration of why it is essential that a plaintiff be held to the pleading standard required by Rule 9(b).

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<sup>1</sup> The Suffolk-Only Defendants adopt and incorporate by reference all of the arguments advanced on behalf of all defendants in the Joint Motion to Dismiss and supporting Memorandum.

<sup>2</sup> Berlex Laboratories, Inc., Forest Pharmaceuticals, Inc., and Reliant Pharmaceuticals, LLC have recently been named in *County of Westchester v. Abbott et al.*, a similar suit filed by the same plaintiff law firm which has not yet been transferred to this proceeding. Purdue Pharma L.P. is not a defendant in that action.

## ARGUMENT

### I. SUFFOLK'S COMPLAINT FAILS TO SATISFY RULE 9(b) AS TO THE SUFFOLK-ONLY DEFENDANTS.

Rule 9(b) requires that a plaintiff alleging fraud must "(1) specify the statements that plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997) (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1127 (2d Cir. 1994)). This requirement applies to each defendant. *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp. 2d 70, 79 (D. Mass. 1998). This Court, in this litigation, held in May 2003 that Rules 8 and 9(b) required that the class action plaintiffs in one of the other consolidated actions "clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." *In re Pharm. Industry Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003).

Suffolk's allegations with respect to the Suffolk-Only Defendants fall far short of the Rule 9(b) standard. Suffolk includes allegations regarding investigations and settlements of other Defendants and involving drugs covered by an entirely different federal health program. None of these allegations has anything to do with the Suffolk-Only Defendants. As to this group of Defendants, Suffolk makes only conclusory allegations that follow the same pattern and are equally vague.

The Amended Complaint claims that each Suffolk-Only Defendant: (1) manufactures and sells prescription drugs with false and inflated AWPs (Am. Compl. ¶¶ 30, 35, 47, 48); (2) reported inflated prices, which constituted "fraud" (*id.* ¶¶ 182-87; 213-17, 280-83, 284-88); and (3) participated in "Manufacturer-Publisher Enterprises," three alleged associations-in-fact

which contain allegations identical to the scores of other alleged associations-in-fact involving other manufacturers. (*Id.* ¶¶ 341(h), (m), (x) & (y)). These sole contentions regarding the Suffolk-Only Defendants fail to satisfy Rule 9(b).

First, these vague and conclusory allegations are contrary to this Court's directive: "You've got to meet 9(b) requirements. You've got to particularize exactly what drugs, exactly what the fraud is, what plaintiffs paid for what drugs." (Tr. of Jan. 13, 2003 Oral Arg. at 74.) Suffolk does not offer any facts which would support a contention that the AWPs for the Suffolk-Only Defendants' drugs were either false or fraudulent, or indeed with respect to Purdue's drug, OxyContin, any AWP at all. Nor does Suffolk explain how its proffered "Estimated True AWP" is calculated.<sup>3</sup>

Second, Suffolk fails to allege any facts supporting the proposition that the AMPs ("average manufacturer prices") reported by the Suffolk-Only Defendants were in any way inaccurate or that therefore the rebates paid by the Suffolk-Only Defendants under Medicaid were somehow reduced by fraudulently reported AMPs. Indeed, if it is Suffolk's position that these AMPs were artificially inflated (*see Am. Compl. ¶¶ 360, 370*), then Suffolk would have received *higher* rebates than it was entitled to receive. How, then, can Suffolk have been damaged?

Third, Suffolk baldly claims that, separate and apart from the AWP inflation claim, the Suffolk-Only Defendants failed to properly report the "Best Price" for the alleged drugs. (Am. Compl. ¶¶ 185, 215, 281, 286.) However, Suffolk presents no evidence to support those claims. Confessing the obvious absence of support for any such claim, Suffolk instead requests that its

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<sup>3</sup> For example, Suffolk alleges a purported spread of 26% between Forest's Celexa AWP and Suffolk's "Estimated True AWP" for Celexa without explaining why that particular spread is fraudulent or from what it is derived.

mere concoction of possible claims should allow it to drag the Suffolk-Only Defendants through discovery by which Suffolk would hope to discover some evidence of wrongdoing. (*Id.*) This sort of wishful pleading does not satisfy Suffolk's burden under Rule 9(b).

All other allegations in the Amended Complaint are not specific to the Suffolk-Only Defendants and are devoid of any factual support, direct or indirect, to link the Suffolk-Only Defendants to the alleged wrongful conduct. Thus, they are insufficient under Rule 9(b).

**II. SUFFOLK'S MISPLACED MEDICARE RHETORIC AND ALLEGATIONS REGARDING OTHER DEFENDANTS DO NOT SUPPORT SUFFOLK'S CLAIMS AS TO THE SUFFOLK-ONLY DEFENDANTS.**

Suffolk's attempt to morph issues and facts relating to Medicare Part B into the Medicaid context constitutes a demonstrable sleight-of-hand that should be rejected by this Court. By way of illustration, the Amended Complaint starkly announces that "[e]very free sample of a drug for which a provider bills the government effectively reduces the provider's overall cost for that drug." (Am. Compl. ¶ 90.) While that may be true in the Medicare Part B context for Medicare Part B drugs — where the doctor purchases the drug, administers it to the patient and bills Medicare — the same is not true in the Medicaid context when the drug at issue is not administered by the doctor and is, instead, filled through a prescription at the local drugstore. The "provider" in this context is the drugstore, not the doctor, and the drugstore does not receive free samples from the manufacturer. Even if doctors were to receive samples of the drugs at issue for the Suffolk-Only Defendants, no Medicaid reimbursement would be sought for those drugs. Thus, if a patient who is eligible under Medicaid received the sample from the doctor, the sample provided would *eliminate* a potential Medicaid claim, saving Suffolk the reimbursement expense altogether.

Indeed, Suffolk's Amended Complaint is replete with Medicare-specific allegations,<sup>4</sup> including allegations relating to other Defendants which have nothing whatsoever to do with the Suffolk-Only Defendants. Among other things, Suffolk makes extensive reference to governmental investigations of other Defendants, virtually all of which focus on Medicare issues and marketing practices used when doctors are the purchasers of the drugs in question. Whatever the dubious merits of these allegations, they surely do nothing to bolster Suffolk's otherwise patently-defective allegations as to the Suffolk-Only Defendants under Medicaid. Suffolk's attempt to interject the Suffolk-Only Defendants into these proceedings is unsupported and has absolutely no basis in fact or law.

#### CONCLUSION

For the above reasons, as well as those set forth in the Joint Motion to Dismiss, Suffolk's claims against the Suffolk-Only Defendants should be dismissed with prejudice.

Dated: September 15, 2003

Respectfully submitted,

GIBBONS, DEL DEO, DOLAN, GRIFFINGER &  
VECHIONE

By: Bruce A. Levy  
Bruce A. Levy

One Riverfront Plaza  
Newark, NJ 07102  
(973) 596-4841

Attorneys for Defendant  
Berlex Laboratories, Inc.

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<sup>4</sup> Unlike in the context of Medicare Part B drugs which are tied solely to AWP, with the Medicaid program, defendants are required to report their AMP and "Best Price," figures based on actual sales, and to pay rebates to the States based upon those actual figures. Thus, Suffolk cannot mimic the damage theory alleged with respect to Medicare Part B drug reimbursement.

DORNBUSH MENSCH MANDELSTAM  
& SCHAEFFER, LLP

By: Peter J. Venaglia  
Peter J. Venaglia  
Brian Rafferty

747 Third Avenue  
New York, NY 10017  
(212) 759-3300

Attorneys for Defendant  
Forest Pharmaceuticals, Inc.

MORRISON & FOERSTER LLP

By: Lori A. Schechter  
Lori A. Schechter

425 Market Street  
San Francisco, CA 94105  
(415) 268-7000

Attorneys for Defendant  
Purdue Pharma L.P.

GIBBONS, DEL DEO, DOLAN, GRIFFINGER &  
VECCHIONE

By: Bruce A. Levy  
Bruce A. Levy

One Riverfront Plaza  
Newark, NJ 07102  
(973) 596-4841

Attorneys for Defendant  
Reliant Pharmaceuticals, LLC